IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Marius Filtvedt et al.	)	Examiner: Huong Q. Pham Art Unit: 3772
Serial No.: 10/749,150	)	Atty. Docket No. 49281.1.2
Filed: December 30, 2003	)	
For: DEVICE FOR APPLYING A PULSATING PRESSURE TO A LOCAL REGION OF THE BODY AND THE APPLICATIONS THEREOF	)	

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REVISED APPEAL BRIEF (37 C.F.R § 41.37)

This is an appeal of the Examiner's final rejection of claims 1-27, 29, 30, 32-43, 47-52, 54-58, 60-67, and 69-82, in the Final Office Action issued on May 7, 2007 and is a revised and replacement Appeal Brief of that originally filed on January 18, 2008. This is responsive to the Notification of Non-Compliant Appeal Brief mailed 02/07/2008.

REAL PARTY IN INTEREST.

The real party in interest is THERMONOR AS, the assignee of record.

RELATED APPEALS AND INTERFERENCES.

None.

STATUS OF CLAIMS.

Claims 1-27, 29, 30, 32-52, 54-67, and 69-82 are pending in this case. Claims 44-46 and 59 have been withdrawn; claims 28, 31, 53, and 68 have been cancelled; and

claims 1-27, 29, 30, 32-43, 47-52 54-58, 60-67 and 69-82 have been finally rejected. Applicants are appealing the Examiner's final rejection of claims 1-27, 29, 30, 32-43, 47-52, 54-58, 60-67, and 69-82. A copy of the appealed claims is provided in the Claims Appendix near the end of this document.

STATUS OF AMENDMENTS.

Applicants have made no amendments to the claims since the May 7, 2007 Final Office Action. In response to the Final Office Action, Applicants filed their Notice of Appeal on August 7, 2007, without further amendment.

SUMMARY OF CLAIMED SUBJECT MATTER.

The subject matter defined in independent claim 1 finds support in both the specification and the drawings. The device for applying a pulsating pressure to a local region of the body finds support, for example, at page 30, lines 1-11 and in Figure 1 as reference number 3. The pressure chamber in to which a limb of the body can be placed to seal it from external conditions finds support, for example, at page 30, lines 2-4 and in Figure 1 as reference number 4. Immersing a limb in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb finds support, for example, at page 30, lines 8-9 and generally in Figure 1. An element for generating pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid finds support, for example, at page 7, lines 7-9 and generally in Figure 1. The element being adapted to generate negative pressure for between 1 and 20 seconds and to release negative pressure for between 2 and 15 seconds finds support, for example, at page 10, lines 1-12.

The subject matter defined in independent claim 25 finds support in both the specification and the drawings. The method of applying a pulsating pressure to a local region of the body finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Introducing a limb in to the pressure chamber such that it is sealed from external conditions finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid finds support, for example, at page 6, lines 13-20 and generally in Figure 1. Each pulse of negative pressure being generated for between 1 and 20 seconds and released for between 2 and 15 seconds finds support, for example, at page 10, lines 1-12.

The subject matter defined in independent claim 47 finds support in both the specification and the drawings. The device for applying a pulsating pressure to an area of skin on a limb of a body finds support, for example, at page 27, line 22 through page 28 line 5 in Figure 9 as reference number 3. The pressure chamber into which the limb can be inserted finds support, for example, at page 34, lines 6-16 and in Figure 9 as reference number 4. The barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin finds support, for example, at page 34, lines 6-16 and in Figure 9 as reference number 37. The barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of liquid within the chamber finds support, for example, at page 34,

lines 6-16 and generally in Figure 9. The device including an element or means for generating a pulsating negative pressure within the pressure chamber finds support, for example, at page 34, lines 6-16 and generally in Figure 9. The device including an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin finds support, for example, at page 34, lines 6-16 and generally in Figure 9. The element or means for generating negative pressure being in communication with the inner region but not with the outer region finds support, for example, at page 34, lines 6-16 and generally in Figure 9.

The subject matter defined in independent claim 48 finds support in both the specification and the drawings. The method of treating hypothermia in a human body by applying a pulsating pressure to a local region of that body finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Introducing a limb in to the pressure chamber such that it is sealed from external conditions finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Circulating the liquid via a heat exchanger unit to heat the liquid to a temperature of 40°C or above finds support, for example, at page 24, lines 21-22. Generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa) finds support, for example, at page 20, lines 3-10. Each pulse of negative pressure being generated for between 1 and 20

seconds and released for an interval of between 2 and 15 seconds finds support, for example, at page 13, line 20 through page 14, line 7. The pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid finds support, for example, at page 11, lines 1-5.

The subject matter defined in independent claim 50 finds support in both the specification and the drawings. The method of treating hyperthermia in a human body by applying a pulsating pressure to a local region of that body finds support, for example, at page 38, line 17. Providing a pressure chamber finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Introducing a limb into the pressure chamber such that it is sealed from external conditions finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid finds support, for example, at page 13, line 20 through page 14, line 7 and generally in Figure 1. Circulating the liquid via a heat exchanger unit to cool the liquid to a temperature of 30°C or less finds support, for example, at page 24, lines 23-24. Generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa) finds support, for example, at page 20, lines 3-10. Each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds finds support, for example, at page 13, line 20 through page 14, line 7. The pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid finds support, for example, at page 11, lines 1-5.

The subject matter defined in independent claim 52 finds support in both the specification and the drawings. The method of increasing blood flow to a local region of the body finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Providing a pressure chamber finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Introducing the local region of the body into the pressure chamber such that the local region is sealed from external conditions finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Introducing liquid into the pressure chamber so that the local region of the body is substantially surrounded by and in direct contact with the liquid finds support, for example, at page 6, lines 13-21 and generally in Figure 1. Alternately generating negative pressure for a predetermined time interval of 1 to 20 seconds and releasing negative pressure for a predetermined time interval of 2 to 15 seconds within the chamber finds support, for example, at page 12, lines 1-10. The negative pressure being transmitted to the local region through direct contact with the liquid finds support, for example, at page 6, lines 7-12.

The subject matter defined in independent claim 61 finds support in both the specification and the drawings. The method of applying a pulsating negative pressure to a local region of the body finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Providing a pressure chamber containing a gas finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Introducing a limb into the pressure chamber such that the limb is sealed from external conditions finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber finds support,

for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Continuously supplying a constant negative pressure into the gas pocket finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1. Introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket finds support, for example, at page 12, line 24 through page 13, line 8 and generally in Figure 1 and at page 12, lines 3-7.

The subject matter defined in independent claim 62 finds support in both the specification and the drawings. The method of transferring thermal energy to and from a body finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Providing an enclosure finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Introducing a limb into the enclosure such that the limb is sealed from external conditions finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Introducing thermal exchange liquid into the chamber so that the limb is completely surrounded by and in direct contact with the liquid finds support, for example, at page 13, lines 9-20 and generally in Figure 1. The introduced thermal exchange liquid having a predetermined temperature different than the core body temperature finds support, for example, at page 13, lines 9-20. Circulating the introduced thermal exchange liquid around the surfaces of the limb, the liquid transmitting heat to or from the limb finds support, for example, at page 13, lines 9-20 and generally in Figure 1. Generating a pulsating negative pressure within the enclosure finds support, for example, at page 13, lines 9-20 and generally in Figure 1. The pulsating negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid finds support, for example, at page 13, lines 9-20 and

generally in Figure 1. Generating pulsating negative pressure including alternately generating negative pressure for between 1 and 20 seconds and releasing negative pressure for between 2 and 15 seconds finds support, for example, at page 12, lines 1-10.

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL.

Claims 1, 25, 29-30, 32-33, 52, 54, 62, 64-65, and 69-76 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 3,292,613 to MacLeod ("MacLeod").

Claims 48-51 stand rejected under 35 U.S.C. § 103(a) as obvious over MacLeod in view of U.S. Patent No. 5,683,438 to Grahn ("Grahn") and U.S. Patent No. 3,878,839 to Norton et al. ("Norton").

Claims 47 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Norton.

Copies of each of the above-identified references are attached in the Evidence Appendix near the end of this document.

ARGUMENT.

A. The Board Should Reverse the Final Office Action's Rejection of Claims 1, 25, 29-30, 32-33, 52, 54, 62, 64-65, and 69-76 Because MacLeod Does Not Anticipate Them Under 35 U.S.C. § 102(b) or Render Them Obvious Under 35 U.S.C. § 103(a).

1. *MacLeod Does not Disclose the Negative Pressure Pulses of Specific Duration Recited in Independent Claims 1, 25, 52, and 62.*

Applicants respectfully submit that the Final Office Action errs in asserting that MacLeod discloses negative pressure pulses of specific duration as recited in independent claims 1, 25, 52, and 62. The relevant limitations in those claims are as

follows:

- claim 1 – "wherein an element is provided to generate pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid, the element being adapted to generate negative pressure for *between 1 and 20 seconds* and to release negative pressure for *between 2 and 15 seconds*"
- claim 25 – "generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid, wherein each pulse of negative pressure is generated for *between 1 and 20 seconds* and released for *between 2 and 15 seconds*"
- claim 52 – "alternately generating negative pressure for a predetermined time interval of *1 to 20 seconds* and releasing negative pressure for a predetermined time interval of *2 to 15 seconds* within the chamber, the negative pressure being transmitted to the local region through direct contact with the liquid"
- claim 62 – "generating a pulsating negative pressure within the enclosure, the pulsating negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid, wherein generating pulsating negative pressure includes alternately generating negative pressure for *between 1 and 20 seconds* and releasing negative pressure for *between 2 and 15 seconds*"

As can be seen, each claim recites pressure generation for between 1 and 20 seconds and pressure release for between 2 and 15 seconds. Thus, the shortest claimed negative pressure pulse is 3 seconds (1 second generation and 2 seconds release).

The Final Office Action rejects all of these independent claims based on MacLeod. With respect to the claimed pressure pulse durations, the Final Office Action states only,

> "MacLeod (3,292,613) teaches that ' the pressure can be synchronized to the heart beat or can be applied less or more frequenly [sic] and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.' (column 5, lines 9-20). Therefore, the device of Macleod is capable of providing the recited pressures . Note that the rate of the heartbeat is different from one person to another. While the rate of

> the heartbeat of one person might be about every second or more, note that the rate of the heartbeat of another person (for example, a person who is sleeping , or in a state of relaxation, or in a meditation state , etc.) might be much longer than one second."

(Final Office Action at 4.) Applicants agree that MacLeod teaches synchronizing pressure pulses with a patient's heartbeat. However, parting ways with the Final Office Action, Applicants conclude that MacLeod's pressure pulses are significantly shorter than those of independent claims 1, 25, 52, and 62.

For a device that synchronizes pressure pulses with a patient's heartbeat to produce a 3-second pressure pulse, the patient's heart rate would have to be 20 beats per minute. Such a heart rate is pathological and would require urgent care or risk death. Even an Olympic athlete has a heart rate around 40 beats per minute when sleeping, which is double what would be required for the MacLeod device to produce a 3-second pressure pulse. Accordingly, Applicants submit that it is unreasonable to read MacLeod as referring to a patient with a heart rate of 20 beats per minute. Rather, a reasonable reading of MacLeod assumes a heart rate of a normal person—along the lines of 60 beats per minute. Based on this reading, MacLeod teaches pressure pulses that last roughly one second, which is significantly shorter than each of the claimed ranges. Accordingly, Applicants respectfully submit that the Final Office Action's rejection of independent claims 1, 25, 52, and 62 based on MacLeod is improper.

Moreover, the specification of the present application describes several advantages over systems like that of MacLeod, which produce pressure pulses synchronized to a patient's heartbeat. For example, page 21 (lines 15-17)states,

> "In a number of earlier known systems in which an oscillating pressure was applied to a patient, it was thought best to vary pressure in time with the heart beat. The present inventors have found that a longer period to the oscillation is better."

Additionally, the following portions of the specification describe how longer pressure pulses produce remarkable increases in blood velocity without constricting the diameter of the blood vessels:

- "[I]t has been found that a preferred embodiment can improve blood velocity by up to at least 30% in the brachial artery." (Page 15, lines 9-10.)
- "In experiments, an average of at least 50% increase in blood velocity and an increase of 200% in a single subject have been witnessed. By pulsating the pressure, it is believed to facilitate the immediate and repeated increase of blood velocity without inducing a reflex constriction as a result of the venus pooling." (Page 15, lines 10-14.)
- "Figure 4 shows a detailed one minute recording. The negative pressure is built up for 10 seconds and released for 7 seconds (upper panel). The blood velocity in the brachial artery is measured outside the pressure chamber 4. The blood velocity increases to a certain point, about -25 mmHg (-3.4 kPa), before it drops. This is thought to be due to a reflex constriction of the arteries because of the venus pooling. Letting the pressure drop again, facilitates the immediate and repeated increase of blood velocity without the reflex restricting the blood flow as can happen with a constant negative pressure." (Page 31, line 21 through page 32, line 2.)

The test trial discussed on pages 36-38 of the specification cites even more advantages provided by embodiments of the present invention. Accordingly, because Applicants submit that the present invention is patentable over MacLeod, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 1, 25, 52, and 62.

2. *MacLeod Does not Disclose the Negative Pressure Pulses of Even More Specific Duration Recited in Dependent Claims 29-30, 32-33, 54, 64-65, and 69-76.*

Applicants likewise submit that the Final Office Action errs in asserting that negative pressure pulses of more specific duration as recited in dependent claims 29-30, 32-33, 54, 64-65, and 69-76 would have been obvious in light of MacLeod. The

durations recited in these claims are as follows:

- Depending from claim 1:
  - ⇨ claim 69 – "wherein the element is adapted to release negative pressure for between 5 and 10 seconds"
  - ⇨ claim 70 – "wherein the element is adapted to release negative pressure for 7 seconds"
  - ⇨ claim 71 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds"
  - ⇨ claim 72 – "wherein the element is adapted to generate negative pressure for 10 seconds"
  - ⇨ claim 73 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for between 5 and 10 seconds"
  - ⇨ claim 74 – "wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for 7 seconds"
  - ⇨ claim 75 – "wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for between 5 and 10 seconds"
  - ⇨ claim 76 – "wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for 7 seconds"

- Depending from claim 25:
  - ⇨ claim 29 – "wherein each pulse of negative pressure is generated for between 5 and 15 seconds"
  - ⇨ claim 30 – "wherein each pulse of negative pressure is generated for 10 seconds"
  - ⇨ claim 32 – "wherein each pulse of negative pressure is generated for between 5 and 15 seconds" and "wherein the negative pressure is released for an interval of between 5 and 10 seconds at a time to create the pulses of negative pressure"
  - ⇨ claim 33 – "wherein each pulse of negative pressure is generated for 10 seconds" and "wherein the negative pressure is released for 7 seconds at a time to create the pulses of negative pressure"

- Depending from claim 52:
  - ⇨ claim 54 – "wherein the alternately generating and releasing

negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds"

- Depending from claim 62:
  - ⇨ claim 64 – "wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of between about 5 and 15 seconds and releasing the negative pressure for a time interval of between about 5 and 10 seconds"
  - ⇨ claim 65 – "wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds"

As can be seen, the negative pressure pulses of these claims are all significantly longer than those of the independent claims. The shortest would have pressure generation for 1 second and pressure release for 5 seconds (claim 69), resulting in a 6-second negative pressure pulse. The other claims recite longer negative pressure pulses.

The Final Office Action rejects each of these claims based only on unsupported assertions that the claimed negative pressure pulses would have been obvious. Specifically, pages 5-6 of the Final Office Action state,

> "As for claims 29-30, 32-33, 54, 64 –65, 69- 76, note that the claimed time intervals are results of obvious experiments and observations , which are well within the realm of one ordinary skill in the art, and do not provide any unobvious result, and therefore are not patentable over prior art. Note that MacLeod (3,292,613) teaches that ' the pressure can be synchronized to the heart beat or can be applied less or more frequenly [sic] and in regular multiples of a heart beat , for example, during every second or third heart beat....., or the pressure can be applied irregularly with respect to the heartbeat.' (column 5, lines 9-20). Providing this teaching of MacLeod (3,292,613) wherein the pressure can be applied less frequently in regular multiples of a heartbeat (i.e., in about at least more than one second , or longer), the exact optimum time intervals can be defined by obvious experiments and observations to provide optimum results, which are well within the realm of one ordinary

> skill in the art, and which do not provide any unexpected results, and therefore is not patentable over prior art."

Applicants respectfully submit that the evidence of record refutes the assertion that the dependent claims' pressure pulses recited above are obvious. The most important piece of evidence is the Rule 1.132 Affidavit of Erling Bekkestad Rein, submitted on February 15, 2007. In his Affidavit, Mr. Rein details an experiment he conducted to test the efficacy of applying the claimed negative pressure pulses. (Affidavit at 3-11.) Applicants encourage the Board to review this detailed explanation. Based on this experiment, Mr. Rein concludes, "The results show that applying pulses of negative pressure at the claimed intervals has a remarkable impact on blood velocity, while doing so at other intervals does not." (*Id.* at 3.)

Applicants also respectfully submit that secondary considerations (see MPEP 2141(III)) likewise support Applicants' position that the dependent claims' pressure pulses are nonobvious. Mr. Rein's Affidavit notes that he and his co-inventor were able to publish an article titled "Hypothermia During Laparotomy Can Be Prevented by Locally Applied Warm Water and Pulsating Negative Pressure" in the prestigious British Journal of Anaesthesia. This shows that those skilled in the art have taken notice of at least certain aspects of the present invention. Moreover, Mr. Rein's Affidavit also notes that sales of a commercial embodiment of the present invention have earned $500,000—a tribute to the present invention's commercial success. Indeed, Applicants submit that neither the peer recognition nor the commercial success would have resulted if the present invention was nothing more than an obvious extension of MacLeod's 45-year-old technology. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of dependent claims 29-30, 32-33, 54, 64-

65, and 69-76.

B. The Board Should Reverse the Final Office Action's Rejection of Claims 48-51 Because They Are Not Rendered Obvious by MacLeod in View of Grahn and Norton.

Applicants respectfully submit that the Board should reverse the Final Office Action's rejection of claims 48-51 for the same reasons set forth in the previous section. The relevant limitations of independent claims 48 and 50 are as follows:

- claim 48 – "generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for *between 1 and 20 seconds* and released for an interval of *between 2 and 15 seconds* the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid"
- claim 50 – "generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for *between 1 and 20 seconds* and released for an interval of *between 2 and 15 seconds* the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid"

As with independent claims 1, 25, 52, and 62 discussed above, the shortest negative pressure pulse covered by independent claims 48 and 50 is 3 seconds. As is discussed above, MacLeod teaches only shorter pressure pulses. Accordingly, for the same reasons set forth above in connection with independent claims 1, 25, 52, and 62, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 48 and 50.

Moreover, for the same reasons set forth above in connection with dependent claims 29-30, 32-33, 54, 64-65, and 69-76, Applicants respectfully submit that the Final Office Action errs in asserting that negative pressure pulses of more specific duration as

recited in dependent claims 49 and 51 would have been obvious in light of MacLeod. Dependent claims 49 and 51 both recite "wherein the negative pressure is generated for 10 seconds and then released for 7 seconds." For the reasons set forth above, Applicants submit that one skilled in the art would not have found the 17-second pressure pulses of dependent claims 49 and 51 to be an obvious extension of MacLeod. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claims 49 and 51.

C. The Board Should Reverse the Final Office Action's Rejection of Claims 47 and 61 Because Norton Does Not Anticipate Them Under 35 U.S.C. § 102(b).

1. The Final Office Action's Rejection of Claim 61 Does Not Address the Language of Claim 61.

Applicants respectfully submit that the Final Office Action's explanation of the rejection of claim 61 bears no relation to the language of claim 61. Claim 61 is as follows:

> A method of applying a pulsating negative pressure to a local region of the body, comprising:
> providing a pressure chamber containing a gas;
> introducing a limb into the pressure chamber such that the limb is sealed from external conditions;
> partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber;
> *continuously supplying a constant negative pressure into the gas pocket; and*
> *introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce a net positive pressure in the gas pocket.*

The Final Office Action (page 9) rejects claim 61 as being anticipated by Norton and

offers only the following explanation:

> "Norton et al teaches a pressure chamber 31 (figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin (figure 14) to maintain the barrier layer in contact with the area of skin. Note column 9, lines 63-68, and column 10, lines 1-21. Therefore, Norton et al 's device is capable of providing the recited pressures ."

As can be seen, the explanation does not address claim 61's method. For example, it does not address claim 61's "continuously supplying" or "introducing" steps. Accordingly, Applicants respectfully submit that the Final Office Action has not made a prima facie case that Norton anticipates claim 61.

Moreover, Applicants respectfully submit that claim 61 is patentable over Norton. Norton does not disclose either of claim 61's "continuously supplying" or "introducing" steps. The specification of the present application describes benefits associated with these steps as follows:

> "When the pressure drops back to zero (relative to atmospheric pressure), the veins constrict and the blood is forced towards the direction with the lowest resistance to flow. The venous valves will effectively force the blood in the direction towards the heart only. If a positive pressure is added the transmurale pressure will drop. The intramural pressure is much larger in the arteries. This leads to a relative larger constriction of veins compared to arteries, and the veins are "emptied" of blood. The veins are now ready to receive more blood, and the pressure starts to drop again. The microvasculature capillaries also appear to be affected and there is also a possibility that the lymphatic system is affected too, and that lymph flow is increased. Lymphatic circulation is believed to be affected by the pulsating pressure in the same way as the veins because the vessels also have one-way valves. As the vessel walls are even thinner than in the veins, a system operating on the lymphatic system alone may be utilised by operating at lower

> pressures (including positive pressures) but following the same pulsating mode, thereby minimizing the effects on the arteries/veins (because increased blood flow can have a negative effect on oedema etc.)."

(Page 14, lines 18-25.) Accordingly, because claim 61 is patentable over Norton, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claim 61.

2. *The Final Office Action's Rejection of Claim 47 Does Not Address Every Limitation of Claim 47.*

Applicants respectfully submit that the Final Office Action's rejection of claim 47 as anticipated by Norton is improper because it does not address every limitation of claim 47's device. Relevant portions of claim 47 are as follows:

> a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having a flow of liquid within the chamber,
>
> wherein the device includes
>
> . . . .
>
> an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, *the element or means for generating negative pressure being in communication with the inner region but not with the outer region.*

The Final Office Action (page 9) explains its rejection of claim 47 as follows:

> "Norton et al teaches a pressure chamber 31 (figure 6) into which the limb can be inserted, a barrier layer of flexible material 31 housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from a flow of liquid within the chamber, wherein the device includes an element or means for generating a pulsating pressure within the pressure chamber, and an element or means for generating a negative pressure between the barrier layer and the area of skin (figure 14) to maintain the barrier layer in contact with the area of skin. Note

> column 9, lines 63-68, and column 10, lines 1-21. Therefore, Norton et al 's device is capable of providing the recited pressures ."

As can be seen, this explanation does not address the last limitation recited in claim 47—"the element or means for generating negative pressure being in communication with the inner region but not with the outer region." Thus, the Final Office Action does not make a prima facie case supporting the rejection of claim 47.

Moreover, Norton discloses nothing that can generate negative pressure by being in communication with an inner region but not with an outer region. Rather, Norton states,

> "Thus, a continuous suction can be created in the space between the limb and the sealed container by an external evacuation device. One method of achieving this is to enclose the legs and housing units of the system by a vacuum enclosure 84 as shown by the dashed line in FIG. 13 . . . ."

(Norton at 11:19-24.) Norton's vacuum enclosure (84 in FIG. 13) surrounds and is in communication with the entire housing units rather than with only the space between the sealed container (90 in FIG. 14) and the patient's legs. Thus, Norton's device cannot anticipate amended claim 47. Moreover, such an enclosure that encapsulates the entire housing units would be unwieldy compared with a relatively smaller element or means in communication with the inner region but not with the outer region.

Norton also discloses two other ways to maintain a seal between the sealed container and the patient's limb, neither of which anticipate, or render obvious, amended claim 47. First, Norton states,

> "Such seal can be maintained by the use of an adhesive compound on the surface of the sealed container between the container and the limb. However, such a method may be impractical or inappropriate in many situations."

(Norton 11:8-11.) Amended claim 47 is clearly patentable over such a device that uses

adhesive to create a seal. Second, Norton discloses a "self-evacuation system" (see FIG. 14) in which the mechanism that produces the pressure cycle also expels air from between the sealed enclosure and the leg. (*Id.* at 11:29-12:6.) Amended claim 47 is patentable over this device in that amended claim 47 includes a separate element or means for maintaining the barrier layer in contact with the area of skin. For these reasons, Applicants respectfully submit that amended claim 47 is both novel and nonobvious over Norton. Accordingly, Applicants respectfully urge the Board to reverse the Final Office Action's rejection of claim 47.

D. Conclusion

Based on the foregoing, the Board should reverse the rejection of claims 1-27, 29-30, 32-43, 47-52, 54-58, 60-67, and 69-82. This Appeal Brief sets forth reasons why the rejection of claims 1, 25, 29-30, 32-33, 47-52, 54, 61-62, 64-65, and 69-76 should be reversed. Applicants also respectfully submit that claims 2-24, 26-27, 34-43, 55-58, 60, 63, 66-67, and 77-82 should be reversed because they depend from allowable claims.

Respectfully submitted,

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CLAIMS APPENDIX

1. A device for applying a pulsating pressure to a local region of the body, the device comprising a pressure chamber in to which a limb of the body can be placed to seal it from external conditions, whereby in use the limb can be immersed in a liquid contained in the pressure chamber such that the liquid surrounds and is in contact with the limb wherein an element is provided to generate pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid, the element being adapted to generate negative pressure for between 1 and 20 seconds and to release negative pressure for between 2 and 15 seconds.

2. The device as claimed in claim 1, wherein the pressure chamber comprises an elongate housing having an opening for receiving the limb and a seal arranged around the opening for sealing against the limb.

3. The device as claimed in claim 2, wherein the elongate housing is a cylindrical or box-shaped housing.

4. The device as claimed in claim 2, wherein an inlet and outlet are provided in the housing for introducing and discharging the liquid into and out of the chamber.

5. The device as claimed in claim 4, wherein the inlet and outlet are in communication with each other via a fluid path that is defined by internal walls of the chamber and the surface of the limb once it has been introduced into the chamber, such

that in use liquid flows from the inlet into the chamber, circulates around and in contact with the surface of the limb and is then discharged via the outlet.

6. The device as claimed in claim 4, wherein a liquid flow transmission means is connected to the pressure chamber via the inlet and outlet to generate a flow of liquid which is circulated within the chamber and around the limb.

7. The device of claim 6, wherein the flow transmission means is a pump.

8. The device as claimed in claim 6, wherein the flow transmission means is connected to the pressure chamber via the inlet and outlet to generate a flow of liquid which is circulated within the chamber and around the limb.

9. The device as claimed in claim 1, wherein the liquid is circulated through a heat exchanger unit before it enters the pressure chamber to control the temperature of the liquid.

10. The device as claimed in claim 9, wherein the heat exchanger unit comprises a plurality of heat exchanger tubes housed within a water bath.

11. The device as claimed in claim 1, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

12. The device as claimed in claim 4, wherein the element comprises a

pulsating means for generating pulses of pressure within the chamber.

13. The device as claimed in claim 6, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

14. The device as claimed in claim 9, wherein the element comprises a pulsating means for generating pulses of pressure within the chamber.

15. The device as claimed in claim 1, wherein the element comprises one or more connections that are provided in an upper region of the pressure chamber, coupled via a Y-connector, to communicate the chamber with a pressure source which is at a pressure different from atmospheric pressure for regulating the pressure within the chamber.

16. The device as claimed in claim 15, wherein said pressure source is a suction device.

17. The device as claimed in claim 16, wherein said pressure source is set to create a negative pressure of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa).

18. The device as claimed in claim 17, wherein a valve is provided in connection with the pressure chamber to bleed air at intervals into the pressure chamber to thereby generate the pulses of negative pressure.

19. The device as claimed in claim 18, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for between 2 and 15 seconds at a time.

20. The device as claimed in claim 19, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for between 5 and 10 seconds at a time.

21. The device as claimed in claim 20, wherein the valve is controlled by a timer system to bleed air into the pressure chamber for 7 seconds at a time.

22. The device as claimed in claim 18, wherein the valve is controlled by the timer system to be closed for between 1 and 20 seconds at a time to allow build up of negative pressure.

23. The device as claimed in claim 22, wherein the valve is controlled by the timer system to be closed for between 5 and 15 seconds at a time to allow build up of negative pressure.

24. A device as claimed in claim 18, wherein the valve is controlled by the timer system to be closed for 10 seconds at a time to allow build up of negative pressure.

25. A method of applying a pulsating pressure to a local region of the body

comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid; and

generating a pulsating negative pressure within the chamber and transmitting the pulses of negative pressure to the limb directly via the liquid, wherein each pulse of negative pressure is generated for between 1 and 20 seconds and released for between 2 and 15 seconds.

26. The method as claimed in claim 25, wherein pulses of negative pressure of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa) are generated within the pressure chamber.

27. The method as claimed in claim 26, wherein pulses of negative pressure of -40 mmHg (-5.3 kPa) are generated within the pressure chamber.

29. The method as claimed in claim 25, wherein each pulse of negative pressure is generated for between 5 and 15 seconds.

30. The method as claimed in claim 29, wherein each pulse of negative pressure is generated for 10 seconds.

32. The method as claimed in claim 29, wherein the negative pressure is released for an interval of between 5 and 10 seconds at a time to create the pulses of negative pressure.

33. The method as claimed in claim 30, wherein the negative pressure is released for 7 seconds at a time to create the pulses of negative pressure.

34. The method as claimed in claim 25, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

35. The method as claimed in claim 26, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

36. The method as claimed in claim 29, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

37. The method as claimed in claim 32, wherein the liquid is circulated within the pressure chamber to generate a flow of liquid which is in direct contact with the limb.

38. The method as claimed in claim 25, wherein the temperature of the liquid

is controlled by a heat exchanger unit to be at a temperature either above or below the core body temperature of the patient.

39. The method as claimed in claim 38, wherein the liquid is maintained at a temperature of less than 30°C whilst the pulsating pressure is applied to the limb.

40. The method as claimed in claim 39, wherein the liquid is maintained at a temperature of less than 10°C whilst the pulsating pressure is applied to the limb.

41. The method as claimed in claim 38, wherein the liquid is maintained at a temperature greater than 43.5°C whilst the pulsating pressure is applied to the limb.

42. The method as claimed in claim 41, wherein the liquid is maintained at a temperature greater than 45°C whilst the pulsating pressure is applied to the limb.

43. The method as claimed in claim 24, wherein said method is being applied to the limb of the patient to control or regulate the temperature of the patient.

47. A device for applying a pulsating pressure to an area of skin on a limb of a body comprising

a pressure chamber into which the limb can be inserted,

a barrier layer of flexible material housed within that chamber for form-fitted engagement against the skin, the barrier layer defining an inner region within the pressure chamber for receiving the limb which is separated from an outer region having

a flow of liquid within the chamber,

wherein the device includes

an element or means for generating a pulsating negative pressure within the pressure chamber, and

an element or means for generating a negative pressure between the barrier layer and the area of skin to maintain the barrier layer in contact with the area of skin, the element or means for generating negative pressure being in communication with the inner region but not with the outer region.

48. A method of treating hypothermia in a human body by applying a pulsating pressure to a local region of that body comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure, chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid;

circulating the liquid via a heat exchanger unit to heat the liquid to a temperature of 40°C or above; and

generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid.

49. The method of treating hypothermia in a human body as claimed in claim 48, wherein the negative pressure is generated for 10 seconds and then released for 7 seconds.

50. A method of treating hyperthermia in a human body by applying a pulsating pressure to a local region of that body comprising the steps of:

providing a pressure chamber;

introducing a limb in to the pressure, chamber such that it is sealed from external conditions;

filling or partially filling the pressure chamber with a liquid to immerse the limb in the liquid so that it is substantially surrounded by and in contact with the liquid;

circulating the liquid via a heat exchanger unit to cool the liquid to a temperature of 30°C or less; and

generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for between 1 and 20 seconds and released for an interval of between 2 and 15 seconds the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid.

51. The method of treating hyperthermia in a human body as claimed in claim 50, wherein the negative pressure is generated for 10 seconds and then released for 7 seconds.

52. A method of increasing blood flow to a local region of the body, comprising:

providing a pressure chamber;

introducing the local region of the body into the pressure chamber such that the local region is sealed from external conditions;

introducing liquid into the pressure chamber so that the local region of the body is substantially surrounded by and in direct contact with the liquid; and

alternately generating negative pressure for a predetermined time interval of 1 to 20 seconds and releasing negative pressure for a predetermined time interval of 2 to 15 seconds within the chamber, the negative pressure being transmitted to the local region through direct contact with the liquid.

54. The method of claim 52, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds.

55. The method of claim 52, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure between about -20mmHg and -80mmHg and releasing the negative pressure.

56. The method of claim 55, wherein the alternately generating and releasing

pulses of negative pressure within the chamber comprises alternately generating a negative pressure of about -40mmHg and releasing the negative pressure.

57. The method of claim 52, wherein the introducing liquid into the pressure chamber comprises introducing liquid having a temperature different than the core body temperature.

58. The method of claim 52, further comprising the step of circulating the liquid around the surfaces of the local region of the body to transfer heat to or from the local region.

60. The method of claims 52, wherein the local region is a limb.

61. A method of applying a pulsating negative pressure to a local region of the body, comprising:

providing a pressure chamber containing a gas;

introducing a limb into the pressure chamber such that the limb is sealed from external conditions;

partially filling the pressure chamber with a liquid so that the limb is substantially surrounded by and in direct contact with the liquid while leaving a gas pocket above the liquid in an upper region of the chamber;

continuously supplying a constant negative pressure into the gas pocket; and

introducing a positive pressure into the gas pocket for between 2 and 15 seconds to temporarily release negative pressure within the chamber and to temporarily produce

a net positive pressure in the gas pocket.

62. A method of transferring thermal energy to and from a body, comprising:

providing an enclosure;

introducing a limb into the enclosure such that the limb is sealed from external conditions;

introducing thermal exchange liquid into the chamber so that the limb is completely surrounded by and in direct contact with the liquid, the introduced thermal exchange liquid having a predetermined temperature different than the core body temperature;

circulating the introduced thermal exchange liquid around the surfaces of the limb, the liquid transmitting heat to or from the limb; and

generating a pulsating negative pressure within the enclosure, the pulsating negative pressure being transmitted to the limb through direct contact with the thermal exchange liquid, wherein generating pulsating negative pressure includes alternately generating negative pressure for between 1 and 20 seconds and releasing negative pressure for between 2 and 15 seconds.

63. The method of claim 62, wherein generating the pulsating pressure comprises alternately generating and releasing a negative pressure within the enclosure.

64. The method of claim 63, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of between about 5 and 15 seconds and releasing the

negative pressure for a time interval of between about 5 and 10 seconds.

65. The method of claim 64, wherein the alternately generating and releasing negative pressure within the chamber comprises alternately generating negative pressure for a time interval of about 10 seconds and releasing the negative pressure for a time interval of about 7 seconds.

66. The method of claim 62, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure between about -20mmHg and -80mmHg and releasing the negative pressure.

67. The method of claim 66, wherein the alternately generating and releasing pulses of negative pressure within the chamber comprises alternately generating a negative pressure of about -40mmHg and releasing the negative pressure.

69. The device as claimed in claim 1, wherein the element is adapted to release negative pressure for between 5 and 10 seconds.

70. The device as claimed in claim 1, wherein the element is adapted to release negative pressure for 7 seconds.

71. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds.

72. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds.

73. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for between 5 and 10 seconds.

74. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for between 5 and 15 seconds and to release negative pressure for 7 seconds.

75. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for between 5 and 10 seconds.

76. The device as claimed in claim 1, wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for 7 seconds.

77. The device as claimed in claim 1, wherein the liquid is water.

78. The device as claimed in claim 16, wherein said suction device is a vacuum pump or vacuum line.

79. The device as claimed in claim 17, wherein said pressure source is set to create a negative pressure of -40 mmHg (-5.3 kPa).

80. The device as claimed in claim 18, wherein the valve is provided between said chamber and said pressure source.

81. The method of treating hypothermia in a human body as claimed in claim 48, wherein said pulses of negative pressure within the chamber are -40 mmHg (-5.3 kPa).

82. The method of treating hyperthermia in a human body as claimed in claim 50, wherein the pulses of negative pressure within the chamber are -40 mmHg (-5.3 kPa).

EVIDENCE APPENDIX

1. U.S. Patent No. 3,292,613 to MacLeod, first cited by Examiner in an Office Action dated June 14, 2006.

2. U.S. Patent No. 3,094,983 to MacLeod, first cited by Examiner in an Office Action dated June 14, 2006.

3. U.S. Patent No. 5,683,438 to Grahn, first cited by Examiner in an Office Action dated June 14, 2006.

4. U.S. Patent No. 3,878,839 to Norton et al., first cited by Examiner in an Office Action dated June 14, 2006.

5. U.S. Patent No. 3,896,794 to McGarath, first cited by Examiner in an Office Action dated June 14, 2006.

6. U.S. Patent No. 4,186,732 to Christoffel, first cited by Examiner in an Office Action dated June 14, 2006.

7. Rule 1.132 Affidavit of Erling Bekkestad Rein submitted on February 15, 2007.

RELATED PROCEEDINGS APPENDIX

None.